SIEMENS Healthineers

Urgent Field Safety Notice

POC 23-004.A.OUS

December 2022

epoc® Blood Analysis System

pO_2 High Recovery in Quality Control When Adjusted for Barometric Pressure

Our records indicate that your facility may have received the following product:

Table 1. Affected Products

Product Description	Siemens Material Number (SMN)	Unique Device Identification (UDI-DI)	Host Software Version /Sensor Configuration
epoc Host 2	10736387	00809708052898	3.37.3/41.1
epoc Host 2, Canada	10736388	00809708069117	
epoc Host 2, China	10736389	00809708097219	
epoc Host 2, Japan	10736390	00809708075576	
epoc Host 2, Refurbished	10736393	00809708053901	
epoc Host 2, Canada, Refurbished	10736394	00809708069124	
epoc Host 2, Japanese, Refurbished	10736395	00809708075583	
epoc Host 2, Chinese, Refurbished	10736433	00809708097226	
epoc Host 2, US (MC55X)	11413524	00630414606460	
epoc Host 2, ROW (MC55X)	11413528	00630414606378	
epoc Host 2, India (MC55X)	11413541	00630414608617	
epoc Host 2, China (MC55X)	11413542	00630414608624	
epoc Host 2, Japan (MC55X)	11413543	00630414608532	
epoc Host 2 (MC55X) - US - Refurbished	11413601	00630414615004	
epoc Host 2 (MC55X) - ROW - Refurbished	11413602	00630414614885	
epoc Host 2 (MC55X) - India - Refurbished	11413603	00630414614762	
epoc Host 2 (MC55X) - Japan - Refurbished	11413604	00630414614892	
epoc NXS Host, US	11413475	00630414606095	4.10.6/41.1
epoc NXS Host, EU	11413497	00630414605760	
epoc NXS Host, Japan	11413498	00630414605814	
epoc NXS Host, Canada	11413506	00630414605821	
epoc NXS Host, ROW	11413518	00630414605678	
epoc NXS Host, China-Korea	11413583	00630414612447	

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Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of an issue with the products indicated in **Table 1** above and provide instructions on actions that your facility must take.

Siemens Healthcare Diagnostics Inc. has confirmed an issue through complaint investigation. The issue has the potential to affect the recovery of pO_2 in quality control (QC) at elevation with barometric pressures <730 mmHg on epoc sensor configuration 41.1, epoc Host 2 SW Version 3.37.3 and epoc NXS Host SW Version 4.10.6, which were released on 17 October 2022.

epoc system software running sensor configuration and software version as indicated in Table 1 may exhibit pO_2 high recovery in QC when performing the manual calculation adjustment for barometric pressure as referenced in the epoc System Manual.

The following are NOT affected by this issue:

- QC tests at barometric pressures equal to or above 730 mmHg (97 kPa).
- The pO_2 blood results for sensor configuration 41.1.
- All other analytes other than pO_2 in blood and Quality Assurance (QA) test modes for sensor configuration 41.1.

This issue is due to the lack of inclusion of barometric pressure data at <730 mmHg in sensor configuration 41.1.

Risk to Health

In a worst-case scenario there could be a delay in reporting pO_2 in patient blood samples from a critically ill patient. This could delay the evaluation and management of respiratory or metabolic compromise with attendant complications. No erroneous results will be generated; therefore, retrospective review of test results is not necessary.

Actions to be Taken by the Customer

- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you are a distributor, please ensure your customers receive this UFSN letter.
- If you perform QC tests at barometric pressures equal to or above 730 mmHg (97 kPa), no additional action is required.
- If you perform QC tests at barometric pressures less than 730 mmHg (97 kPa), apply barometric correction factors before comparing the gas readings with the published value assignments. pO_2 readings need to be corrected as follows:
  - $pO_2^{corrected} = pO_2^{reading} * \left(1.093 - (0.000123 * BP[mmHg])\right) + (0.059 * BP[mmHg]) - 46.1$
  - A sample calculation is as follows, where the $pO_2^{reading}$ is 150mmHg and the BP is 630mmHg

$$pO_2^{corrected} = 150 * \left(1.093 - (0.000123 * 630)\right) + (0.059 * 630) - 46.1$$
$$= 143.4 \text{ mmHg}$$

*****Important Note***** The above barometric correction factor should be applied only to epoc System Software sensor configuration 41.1, epoc Host[2] SW Version 3.37.3 and epoc NXS Host SW Version 4.10.6, which expires June 12, 2023. Following the expiration of this sensor configuration and the software version refer to the epoc System Manual Section 9.5.1 for the appropriate Barometric Correction factor to apply.

- Please review this letter with your Medical Director.
- Please retain this letter with your laboratory records and forward this letter to those who may have received the affected product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Technical Solution Center or your local Siemens Healthineers technical support representative.

Additional Information

epoc is a trademark of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

epoc® Blood Analysis System pO_2 High Recovery in Quality Control
When Adjusted for Barometric Pressure

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 23-004.A.OUS dated December 2022 regarding epoc® blood analysis system pO_2 high recovery in quality control when adjusted for barometric pressure. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the UFSN instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Please send a scanned copy of the completed form via email to cruinnfsngroup@cruinn.ie or to fax this completed form to the Customer Care Center at 01 6297401.

If you have any questions, contact your local Siemens Healthineers technical support representative.

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